



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/085,738	02/28/2002	Kevin S. Weadock	15314 (ETH-1636)	8872
7590 05/02/2006				
Scully, Scott, Murphy & Presser		EXAMINER		
400 Garden City Plaza		EREZO, DARWIN P		
Garden City, NY 11530				
		ART UNIT	PAPER NUMBER	
		3731		

DATE MAILED: 05/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

88

Office Action Summary	Application No. 10/085,738	Applicant(s) WEADOCK ET AL.	
	Examiner Darwin P. Erez	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 and 14-43 is/are pending in the application.
- 4a) Of the above claim(s) 3, 10, 11, 16-28 and 34-37 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 4-9, 14, 15, 29-33 and 38-43 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

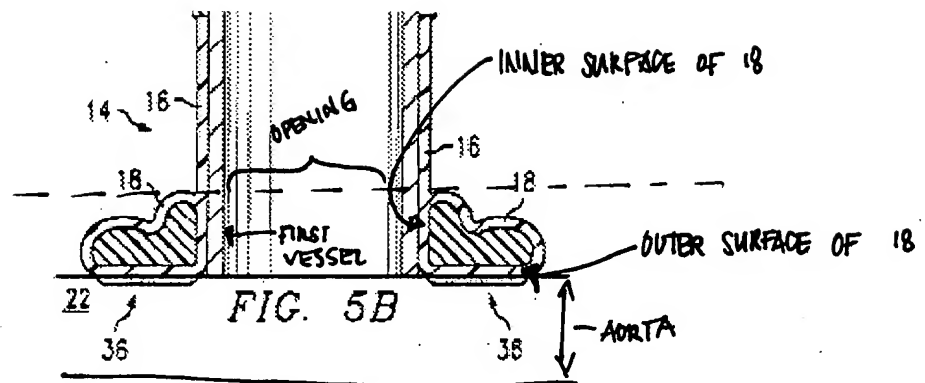
1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 2, 7-9, 14, 15, 29-33 and 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,117,147 to Simpson et al. in view of US 2001/0044631 A1 to Akin et al.

As to claims 1, 2 and 7, Simpson still discloses a device for creating an end-to-side anastomosis (col: 1, lines 6-9), including a body **18** fabricated from a sponge material. Body **18** is viewed as a sponge because it is formed from a polymer material that is impregnated with a liquid drug (col. 3, lines 17-24), which meets the Applicant's definition (and the common definition) of a sponge.

Simpson also teaches a disk-shaped body **18** having an opening (as shown in the figure below) that is configured to contact an outer surface of graft **10** (at the location shown in the figure below); wherein a first securing means secures graft **10** to the opening (securement means could easily be friction fit since graft **10** is contacting the inner surface of the opening) and a second securing means (glue; col. 4, lines 18-23) for securing a portion of the second vessel (aorta) to an outer surface of body **18** (the lower portion of the body).



Simpson's sponge material is not resorbable, but Akin teaches that the advantage of having a sutureless anastomotic fitting be resorbable is that when it disintegrates, a healed/completely physiologic anastomosis is left behind having no foreign body to contend with the human body's natural functioning (paragraph [0128]). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to form Simpson's sutureless anastomosis disc out of a resorbable material in order to allow the vessel junction to heal normally and to be free from any foreign bodies or substances, as taught by Akin.

As to claim 8, Simpson discloses attaching a graft vessel "to a side wall of a target vessel at an opening in the side wall" with glue (col. 1, lines 6-8). Therefore, the glue will be at and around the opening of the side wall of the target vessel.

As to claim 9, the adhesive is applied to the surface of disk-shaped sponge **18** and will necessarily fill in the interstices of the polymer.

As to claims 14 and 15, Simpson discloses impregnating the polymer with an anastomosis modulating agent (col. 3, lines 18-23).

As to claims 29-31, 33 and 41, Simpson teaches the method of using the device 14 for anastomosis³; wherein a portion of the first vessel is attached to the body 18/16, wherein the body is viewed as a sponge (see the rejection to claim 1); wherein the body has an opening that receives the outer surface of the first vessel, the body further having an outer surface that is configured to contact/attach/align to a hole in the outer surface of the aorta; and creating an anastomosis within the body (see rejection to claim 1 and figure above).

As to claim 32, Simpson shows holes that are still formed after the second portion of the second vessel is attached to the body.

As to claims 42 and 43, Fig. 6 shows that blood will flow through both of the anastomosed vessels, as Simpson's cuffs are intended to join two vessels together within the human vascular system.

3. Claims 4, 5, 38 and 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of Akin et al., and in further view of US 6,019,788 to Butters et al.

Simpson teaches securing the opening to a portion of the first vessel by sliding the device over the first vessel. Thus, the device is secured to the first vessel via friction fit. Simpson is silent with regards to an adhesive securing the first vessel to the device. However, Butters teaches a similar device that is used to secure a first vessel to a second vessel; wherein adhesive is used to secure the outer surface of the first vessel to the inner surface of an opening in the device (col. 7, lines 32-38). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was

Art Unit: 3731

made to modify the device and method of Simpson to include adding an adhesive to secure an outer surface of the first vessel to the inner surface of the opening because it would reinforce the anastomosis and help prevent the first vessel from detaching from the second vessel.

4. Claims 6 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Simpson et al. in view of Akin et al., and in further view of US 2002/0065545 A1 to Leonhardt et al.

The above combination of Simpson/Akin discloses all of the claimed features of the invention (as detailed above), including gluing between body **18** and graft vessel **10**. However, the modified Simpson invention fails to disclose using a balloon catheter to urge the outer surface of graft vessel against body, compressing the adhesive between them. However, Leonhardt disclose a graft vessel **24** and a body (**10**, aorta) and discloses inserting and expanding a balloon inside of graft vessel in order to urge the outer surface of the graft vessel against body **10** to sandwich the adhesion (glue, 56) therebetween (paragraphs [0027, 0028, 0030, 0060, 0083]; Figs. 1, 9d, 10a).

Leonhardt teaches that one should use a balloon catheter in order to secure the outside surface of graft vessel ("spring means" 26 specifically and member 24 generally) to the interior surface of body (10) (paragraph [0030], last sentence). Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to employ a balloon catheter to better secure vessel (10) to body (18), sandwiching adhesive therebetween, as taught by Leonhardt, because a balloon catheter expands the inner

member towards the outer member and will cause them to touch and be secured to each other by glue.

Response to Arguments

5. Applicant's arguments filed 2/10/06 have been fully considered but they are not persuasive.

The applicant argued that Simpson fails to teach a body that receives and contacts an outer surface of first or second vessel as recited in claims 1 and 20. This is not persuasive because as stated in the rejections above and shown in the figure above, Simpson teaches a body **18** that has an inner surface that defines an opening and receives an inner surface of the first vessel. The outer surface of body **18**, as shown in the figure above, is also in contact with the outer surface of the aorta. Thus, the outer surface of body **18** receives the outer surface of the aorta.

With regards to the Simpson reference allegedly teaching away from using a resorbable material, this argument is not persuasive. Simpson merely states the various known connectors in the art and does not disclose that his reference will not be enabled with a resorbable material. Furthermore, the arguments for desiring a resorbable material between an "intravascular" and "extravascular" device is not persuasive since it would also be beneficial to make a resorbable extravascular device as it would allow the device to be absorbed into the body over time without requiring an additional surgery to remove said device.

6. Applicant's arguments with respect to claims 4, 5, 38 and 39 have been considered but are moot in view of the new ground(s) of rejection. The new grounds of rejection were necessitated by the amendments to the independent claims.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darwin P. Erezzo whose telephone number is (571) 272-4695. The examiner can normally be reached on M-F (7:30-4:00).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan T. Nguyen can be reached on (571) 272-4963. The fax phone

Art Unit: 3731

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

de


GLENN K. DAWSON
PRIMARY EXAMINER